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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,406	10/12/2004	Peter Stewart Weisner	PZ0218	9916
36335	7590	11/29/2005	EXAMINER	
AMERSHAM HEALTH IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231			BERMAN, JACK I	
			ART UNIT	PAPER NUMBER
			2881	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

AK

Office Action Summary	Application No. 10/511,406	Applicant(s) WEISNER ET AL.	
	Examiner Jack I. Berman	Art Unit 2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/12/04</u> . | 6) <input type="checkbox"/> Other: ____. |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czapinski et al. in view of Bruno et al. and Litt. Czapinski et al. discloses a device for producing a fluid containing a radioactive constituent, the device comprising: a shielded chamber (10) within which is located an isotope container housing a radioactive isotope (sterile generator 12, described at lines 50-52 in column 1 as the generator disclosed by the patent to Bruno et al.), the shielded chamber including first and second fluid connections to opposing ends of the isotope container and a fluid conduit extending from each of the first and second fluid connections to a fluid outlet respectively characterized in that the fluid inlet comprises a single spike (70) having a substantially circular cross-section, the spike being adapted to penetrate the rubber seal (membrane 90) of a vial (eluent bottle 75) and the spike having two bores (71, 72), the first bore (71) extending from a first aperture adjacent the tip of the spike to a fluid connection with the

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fluid conduit (hypodermic needle 66 in Figure 4, but referred to as 68 in line 55 of column 2) and the second bore extending from a second, separate aperture in the spike to an air inlet (77). While Czaplinski et al. does not mention filtering the air coming from the inlet, Litt teaches, at lines 60-67 in column 2, that when air is permitted into the vial (eluant vial 40) of a device for producing a fluid containing a radioactive constituent, as in the Czaplinski et al. device, it should be filtered (by means of antibacterial plug 37 having a sterile barrier 38) to ensure sterility of the resulting fluid. Litt further teaches to provide the device with an outer housing (11) which supports the fluid inlet (needle 32) and the fluid outlet (needle 29) and wherein the spike (needle 32) of the fluid inlet projects through an aperture in the outer housing and the outer housing defines a well (14) about the aperture through which the spike (needle 32) projects, the well being structured to receive a vial. It would have been obvious to a person having ordinary skill in the art to apply the teachings of Litt to the Czaplinski et al. device by filtering the air passing through the air inlet and providing Litt's outer housing with a vial well for the vial in order to achieve the sterility and convenience described by Litt.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Czaplinski et al., Bruno et al., and Litt as applied to claims 1-3 above, and further in view of Riely et al. While at lines 60-67 in column 2, Litt cites cotton as an example of an appropriate material for the sterile barrier (38) of the antibacterial plug (37) through which incoming air passes, Riely et al. teaches at lines 14-39 in column 4, that various materials are suitable for use as antibacterial filters. The list of suitable materials includes both cotton (line 22) and polytetrafluoroethylene (line 32), so the use of polytetrafluoroethylene instead of cotton for the filter disk of the Czaplinski et


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al./Bruno et al./Litt apparatus discussed above would have been an obvious substitution of known equivalents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack I. Berman whose telephone number is (571) 272-2468. The examiner can normally be reached on M-F (8:30-6:00) with every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R. Lee can be reached on (571) 272-2477. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jack I. Berman
Primary Examiner
Art Unit 2881

jb
11/27/05